ICS 11.080.01 SLOVENSKÁ TECHNICKÁ NORMA September 2024

STN	**Sterilizácia výrobkov zdravotnej starostlivosti Vlhké teplo Požiadavky na vývoj, validáciu a rutinnú kontrolu sterilizačného procesu zdravotníckych pomôcok (ISO 17665: 2024)**	**STN EN ISO 17665** 85 6532

Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/24

Rozpracovaná prekladom.

Obsahuje: EN ISO 17665:2024, ISO 17665:2024

Oznámením tejto normy sa ruší
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EN ISO 17665

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Supersedes EN ISO 17665-1:2006, CEN ISO/TS 17665-2:2009

English Version

Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)

Stérilisation des produits de santé - Chaleur humide - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux (ISO 17665:2024)

Sterilisation von Produkten für die Gesundheitsfürsorge - Feuchte Hitze - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 17665:2024)

This European Standard was approved by CEN on 3 December 2023.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN ISO 17665:2024) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17665-1:2006 and CEN ISO/TS 17665-2:2009.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA or ZB, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 17665:2024 has been approved by CEN as EN ISO 17665:2024 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail. In this context, the definition of ‘medical device’ in this standard is a modified version of the definition prepared by the Global Harmonization Task Force with modification to the Note in the definition.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — – Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the medical device is safe and performs as intended after treatment. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This General Safety and Performance Requirement is addressed only with regard to devices for which treatment by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of a specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of a specific microbial state using moist heat are not covered.
11.4 first sentence only	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility by moist heat are not covered. Evidence that the integrity of the packaging

General Safety and Performance Requirements of Regulation (EU) 2017/745	**Clause(s) / sub-clause(s) of this EN**	**Remarks / Notes**
		is maintained to the point of use is not covered.
11.5	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to attainment of sterility using moist heat are not covered.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 11140-1	ISO 11140-1:2014	Sterilization of health care products — Chemical indicators — Part 1: General requirements	EN ISO 11140-1:2014
ISO 11140-3	ISO 11140-3:2007	Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	EN ISO 11140-3:2009
ISO 11140-4	ISO 11140-4:2007	Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	EN ISO 11140-4:2007
ISO 11140-5	ISO 11140-5:2007	Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	None For applicable standard edition see Column 2
ISO 11140-6	ISO 11140-6:2022	Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers.	EN ISO 11140-6:2022
ISO 11607-1	ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020+A11:2022
ISO 11607-2	ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020+A11:2022
ISO 11737-1	ISO 11737-	Sterilization of health care	EN ISO 11737-1:2018+A1:2021

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
	1:2018/amd1:2021	products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	
ISO 11737-2	ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	EN ISO 11737-2:2020
ISO 11138-1	ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements	EN ISO 11138-1:2017
ISO 11138-3	ISO 11138-3:2017	Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes	EN ISO 11138-3:2017

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document and are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning *in vitro* diagnostic medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZB.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/746, the differences shall be indicated in the Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/746, the definitions set out in this Regulation prevail. In this context, the definition of ‘medical device’ in this standard is a modified version of the definition prepared by the Global Harmonization Task Force with modification to the Note in the definition.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the In vitro Diagnostic Regulation (EU) 2017/746).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be ‘reduced as far as possible’, ‘reduced to a level as low as reasonably practicable’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ‘prevented’ or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

Table ZB.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, performance studies, clinical evidence or post-market performance follow-up.

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
11.2	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. It could also be applied to the development, validation and routine control of a process for attainment of a specific microbial state other than sterility. This General Safety and Performance Requirement is addressed only with regard to devices for which treatment by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European Standard. Design and packaging for maintenance of sterility or another specific microbial state during transportation and storage are not covered. Aspects of manufacture other than those related to attainment of sterility or another specific microbial state using moist heat are not covered.
11.3	4,5,6,7,8,9,10,11,12	This standard provides requirements for the development, validation and routine control of a sterilization process using moist heat for medical devices, including requirements that the sterilized medical device is safe and performs as intended after sterilization. This General Safety and Performance Requirement is addressed only with regard to devices for which sterilization by moist heat is appropriate. This relevant General Safety and Performance Requirement is only partly addressed in this European

General Safety and Performance Requirements of Regulation (EU) 2017/746	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		Standard. Packaging for maintenance of sterility is not covered. Aspects of manufacture other than those related to attainment of sterility using moist heat are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 17665

First edition
2024-03

Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

Stérilisation des produits de santé — Chaleur humide — Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 204, *Sterilization of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition cancels and replaces ISO 17665-1:2006, ISO/TS 17665-2:2009 and ISO/TS 17665-3:2013, which have been technically revised.

The main changes compared to the previous editions are as follows:

— combined ISO 17665-1, ISO/TS 17665-2 and ISO/TS 17665-3 into a single standard.

A list of all parts in the ISO 17665 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A sterile medical device is one that is free of viable microorganisms. International Standards that specify requirements for validation and routine control of sterilization processes require when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions, can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices generally can best be described by an exponential relationship between the number of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism can survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be ensured and the expression of sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

The process variables for a moist heat sterilization process, i.e. those which contribute towards microbial lethality, are exposure to adequate temperature for a prerequisite time in the presence of moisture. Moist heat sterilization can be utilised as a saturated steam process, where saturated steam is allowed to directly contact all surfaces to be sterilized, or as a contained product sterilization process, where steam, steam mixed with air or other gas, or hot water under pressure are used as the heating medium in order to generate moist heat within the sealed contained product. The term saturated steam describes a theoretical state in which water and vapour are in equilibrium and that no other gases are present. In practice theoretical saturated steam state conditions are not achieved. Mixtures of steam and NCGs, albeit in very low levels, will be supplied to the sterilizer and employed as the sterilizing agent, moist heat.

This document describes requirements that, if met, will provide a moist heat sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, conformance with the requirements, ensures this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after every sterilization process is complete. Specification of this probability is a matter for regulatory authorities and can vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognise that, for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely, and the equipment is maintained.

Exposure to a properly validated, accurately controlled, monitored and recorded sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of factors including:

a) the microbiological status of either incoming raw materials or components, or both;

b) the validation and routine control of any cleaning and disinfection procedures used on the product;

c) the control of the environment in which the product is manufactured, assembled and packaged;

d) the control of equipment and processes;

e) the control of personnel and their hygiene;

f) the manner and materials in which the product is packaged;

g) the conditions under which product is stored.

The type of contamination on a product to be sterilized varies and this has an impact upon the effectiveness of a sterilization process. It is preferable that products that have been used in a health care setting and that are being presented for sterilization in accordance with the instructions for use (see ISO 17664-1) be regarded as special cases. There is the potential for such products to possess a wide range of contaminating microorganisms (bioburden) and either residual inorganic or organic contamination, or both, in spite of the application of a cleaning process. Hence, particular attention is given to the validation and control of the cleaning and disinfection processes used during processing. The ISO 15883 series provides requirements for and information on automated cleaning and disinfection processes.

This document describes the requirements for ensuring that the activities associated with the process of moist heat sterilization are performed properly. The requirements are the normative parts of this document with which conformance is claimed. The guidance given in the informative Annexes is not intended as checklists for assessing conformance with the requirements of this document. The guidance in the informative Annexes is intended to assist in obtaining a uniform understanding and implementation of the requirements in this document by providing explanations, rationales, examples and methods that are regarded as being suitable means for conforming with the requirements. Methods other than those given in the guidance can be used if they are effective in achieving conformance with the requirements of this document.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities, e.g. calibration, equipment maintenance, product definition, process definition, installation qualification (IQ), OQ and PQ, during which, along with other characteristics, compatibility of product and materials will be ascertained. While the activities required by this document have been grouped together and are presented in a particular order, this document does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programme of development and validation can be iterative. It is possible that performing these different activities will involve a number of either separate individuals or organizations, or both, each of whom undertake one or more of these activities. This document does not specify the particular individuals or organizations who are responsible for carrying out the activities.

The requirements of this document are applicable to all settings where moist heat sterilization of medical devices is carried out. However, this document or part of it can be applied to the moist heat sterilization of other products.

Medical devices processed in an industrial setting can, in certain circumstances, be manufactured using standardised processes that result in product with a known and controlled bioburden prior to sterilization. Medical devices processed in health care facilities can include a wide variety of product with varying levels of bioburden. Appropriate and thorough cleaning and, where necessary for safe handling, decontamination processes, are used prior to presenting product for sterilization. Mixed product loads are common in facilities reprocessing medical devices with throughput volumes dictated by historical and predicted demand for sterile product.

Annex A provides guidance on the principles of moist heat sterilization and provides a rationale for the requirements. Specific guidance for health care facilities is given in Annex F and for industrial applications, in Annex H. The numbering and structure of the clauses in Annex F and Annex H correspond to the numbering and structure of the clauses in the normative requirements section of this document.

An overview of the purpose of each normative section is provided at the beginning of Clauses 5 to 12 (see ISO 14937). Table A.1 summarises the purpose of each normative section and suggests the roles and responsibilities for the organisations and personnel involved in each element of the development, validation and routine control of a moist heat sterilization process and moist heat sterilizer.

International Standard ISO 17665:2024(en)

Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

1 Scope

This document provides requirements for the development, validation and routine control of moist heat sterilization processes for medical devices. It also contains guidance which is intended to explain the requirements set forth in the normative sections. The guidance given is intended to promote good practice related to moist heat sterilization processes according to this document. The application within industrial and health care settings is considered.

1.1 Inclusions

Moist heat sterilization processes covered by this document include, but are not limited to:

a) saturated steam sterilization in which air is removed by passive purging (gravity displacement principle);

b) saturated steam sterilization in which air is removed by active air removal (dynamic air removal, pre-vacuum/fractionated vacuum principle);

c) contained product sterilization in which heat transfer is achieved by steam or steam-air mixtures;

d) contained product sterilization in which heat transfer is achieved by water sprays;

e) contained product sterilization in which heat transfer is achieved by water immersion.

NOTE 1 See Annex D where the processes are explained further.

NOTE 2 Although the scope of this document is limited to medical devices, it specifies requirements and provides guidance that can be applicable to other health care products and industrial applications.

1.2 Exclusions

1.2.1 This document does not specify requirements for development, validation, and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

NOTE 1 See ISO 22442-1, ISO 22442-2 and ISO 22442-3.

NOTE 2 Specific regulations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

1.2.2 This document does not apply to those sterilization processes that are based on a combination of moist heat with other biocidal agents (e.g. formaldehyde) as the sterilizing agent.

1.2.3 This document does not detail a specified requirement for designating a medical device as “sterile.”

NOTE National or regional requirements can designate medical devices as “sterile.” See, for example, EN 556-1 or ANSI/AAMI ST67.

1.2.4 This document does not specify requirements for occupational safety associated with the design and operation of moist heat sterilization facilities.

NOTE There can be applicable national or regional regulations for operational safety.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-3:2017, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11140 (all parts), *Sterilization of health care products — Chemical indicators*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*